REMARKS

Claims 1-15 were pending prior to this amendment. Claims 11-13 have been cancelled for the reasons stated below. As such claims 1-10 and 14 and 15 remain pending.

In the April 1 Office Action the examiner rejected then pending claims, as failing to comply with Unity of Invention. The examiner separated the claims into 6 different groups and required restriction.

Applicant's respectfully traverse this finding as it pertains to the groupings of I-IV, as appears that the examiner's analysis was based on a misunderstanding of the claims and the special technical feature in question, and request that these are examined together. The cancellation of claims 11-13, relating to Groups V and VI, render the remainder of the restriction moot.

37 CFR § 1.475 in laying out Unity of Invention, states that:

(a) An international and a national stage application shall relate to one invention only ***or to a group of inventions so linked as to form a single general inventive concept*** ("requirement of unity of invention"). Where a group of inventions is claimed in an application, the requirement of unity of invention shall be fulfilled ***only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features.*** The expression "special technical features" shall mean those ***technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art***.

(b) An international or a national stage application containing claims to different categories of invention will be considered to have unity of invention if the claims are drawn only to one of the following combinations of categories:

(1) A product and a process specially adapted for the manufacture of said product; or

(2) A product and process of use of said product; or

(3) A product, a process specially adapted for the manufacture of the said product, and a use of the said product; or

(4) A process and an apparatus or means specifically designed for carrying out the said process; or

(5) A product, a process specially adapted for the manufacture of the said product, and an apparatus or means specifically designed for carrying out the said process.

(c) If an application contains claims to more or less than one of the combinations of categories of invention set forth in paragraph (b) of this section, unity of invention might not be present.

The examiner will note that Example 124 of WO02/26723 discloses 4-({[({[(2S)-4-(3,4-Dichlorobenzyl)morpholin-2-yl]methyl}amino)carbonyl]amino}methyl)benzamide ***hydrochloride***. While example 124 discloses ***a salt (the hydrochloride)***, it does not disclose the salt containing a **benzenesulphonate (besylate) anion** which is the subject of each of the pending claims—i.e., the besylate salt of 4-({[({[(2S)-4-(3,4-Dichlorobenzyl)morpholin-2-yl]methyl}amino)carbonyl]amino}methyl)benzamide.

Therefore, applicant respectfully asserts that the current restriction is based on a misunderstanding of the claimed invention, or on too narrow an understanding of Unity of Invention, and is inappropriate under the current facts. As the MPEP 1850 cautions,

> "although lack of unity of invention should certainly be raised in clear cases, ***it should neither be raised nor maintained on the basis of a narrow, literal or academic approach.*** There should be a broad, practical consideration of the degree of interdependence of the alternatives presented, in relation to the state of the art as revealed by the international search or, in accordance with PCT Article 33(6), by any additional document considered to be relevant. If the common matter of the independent claims is well known and the remaining subject matter of each claim differs from that of the others ***without there being any unifying novel inventive concept common to all***, then clearly there is lack of unity of invention. ***If, on the other hand, there is a single general inventive concept that appears novel and involves inventive step, then there is unity of invention and an objection of lack of unity does not arise.*** For determining the action to be taken by the examiner between these two extremes, rigid rules cannot be given and each case should be considered on its merits, the benefit of any doubt being given to the applicant."

(emphasis added).

In this case, the special technical feature of the present invention which not found in the prior art, and which is common to all the claims is the ***besylate salt of the compound*** and not the 4-({[({[(2S)-4-(3,4-Dichlorobenzyl)morpholin-2-yl]methyl}amino)carbonyl]amino}methyl)benzamide per se. The besylate ion of the salt is represented by A^- in the compound of formula (I). This feature is shared by claims 1-10, 14 and 15. The variability found in the claims (excluding claims 11, 12 and 13), only relates to the make-up of the counter ion, ROH, where R is defined as H or C_{1-6} alkyl. The specific molar ratio n is variable from 0.8 to 2.2 to account for the possible molar variations needed to accommodate the specified R groups. Claims 11, 12 and 13 in contrast relate to intermediates useful for making the compound in question.

The special technical feature, i.e., a besylate salt of 4-({[({[(2S)-4-(3,4-Dichlorobenzyl)morpholin-2-yl]methyl}amino)carbonyl]amino}methyl)benzamide with a specific counter ion is common to Groups I, II, III, IV. The fact that these claims fall into various categories of invention does not change the fact that they share the common special technical feature, and thus comply with Unity of Invention, and should properly be examined together. Moreover, Groups I, II, and IV are related under 37 CFR § 1.475 (b)(3), as they relate to "A product (claims 1-5, 7 and 10), a process specially adapted for the manufacture of the said product (claim 6), and a use of the said product(Claims 9, 14 and 15). Group III, although not falling into the delineated list, is a single claim, and merely is a Swiss style claim directed to making a pharmaceutical composition out of the compound of formula (I).

While 37 CFR § 1.475 (c) states that "[i]f an application contains claims to more or less than one of the combinations of categories of invention set forth in paragraph (b) of this section, unity of invention ***might not*** be present" this does not mean that having more than exemplified groupings in 1.475(b) ***must*** results in a lack of unity of invention. To the contrary, the commonality of these groups of the special technical feature of the

specified besylate salt form allows the claims to be considered together under Unity of Invention standards.

In this case, unity of invention is present, and the small number of claims presented does not result in a broad proliferation of claims so as to render examination unduly complicated.

As a practical matter, consideration of all claims 1-10 and 14 and 15 does not present an undue burden in search of examination. Applicant respectfully note that the examiner's statement "[a]dditionally, the vastness of the claimed subject matter, and the complications in understanding the claimed subject matter impose a serious burden on any examination of the claimed subject matter" appears to overstate the complexity of the present situation. As the examiner will appreciate, the claims currently pending relate to search of a single salt of a single compound, with only minor variability of a counter ion.

Concerning the cancelled claims 11, 12 and 13, in contrast to the claims sharing the special technical besylate salt feature, applicant concedes that the intermediates claimed in claims 11, 12 and 13 do not recite the besylate salt of 4-({[({[(2S)-4-(3,4-Dichlorobenzyl)morpholin-2-yl]methyl}amino)carbonyl]amino}methyl)benzamide as a claim element per se. Applicants have therefore cancelled claims 11, 12 and 13, reserving the right to pursue these in separate divisional applications. As these claims have been indicated by the examiner to relate to separate and distinct inventions from the claims remaining in this application, 35 USC 121 is applicable to future divisional practice.

It is respectfully submitted that the regrouping of the restriction is appropriate and is it is therefore requested that the examiner consider claims 1-10, 14 and 15 together, under unity of invention principals.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge any fees or credit any overpayment, particularly including any

fees required under 37 CFR Sect 1.16 or 1.17, and any necessary extension of time fees, to deposit Account No. 07-1392.

Respectfully submitted:

Dated: 1 July 2008

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By: _____

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